CLINICAL RESEARCH STUDIES

From the New England Society for Vascular Surgery

The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair

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Objectives: **The purpose of this study was to compare the eligibility of men and women with infrarenal abdominal aortic aneurysms (AAAs) for on-label endovascular aneurysm repair (EVAR) as part of the clinician-Food & Drug Administration (FDA) collaborative effort, the Characterization of Human Aortic Anatomy Project (CHAP).**

Methods: **Computed tomography (CT) scans with 3D reconstruction from a single institution obtained between July 1996 and December 2009, including standardized measurements by a blinded third-party (M2S, West Lebanon, NH) were examined. For inclusion, abdominal aortic aneurysm (AAA) had to be infrarenal, unrepaired, and >5 cm, or 4 cm to 5 cm if the orthogonal sac diameter was more than twice the aortic diameter at the renal level. Scans were included regardless of subsequent EVAR, open repair, or lack of treatment. One thousand sixty-three unique, unrepaired AAAs were analyzed.**

Results: **Neck length, diameter, and angulation differ for women (*P* < .001) even after adjustment for patient age and AAA size. EVAR eligibility based on device Instructions for Use (IFU) criterion is affected by gender. Neck length <15 mm was found in 47% of men and 63% of women. Neck angulation exceeding 60 degrees was found in 12% of men and 26% of women. Minimum iliac diameter of 6 mm was found in 35% of men and 55% of women. Only 32% of men and 12% of women met all three neck criterion and had iliac lumen diameters >6 mm. Logistic regression modeling shows that older patient age (odds ratio [OR], 0.84 per decade), increased aneurysm diameter (OR, 0.70 per cm), and female gender (OR, 0.4) are each independently associated with decreased odds of meeting all device IFU neck criterion (*P* < .05). EVAR eligibility by neck criterion does not decline significantly until AAA size exceeds 5.5 cm in women and 6.5 cm in men.**

Conclusion: **Women are significantly less likely to meet device IFU criterion for EVAR. Aortic neck criteria and iliac access are important for men and women, but more women than men fail to meet IFU criterion. Devices that accommodate shorter infrarenal AAA neck length will have the greatest impact on expanding on-label EVAR regardless of gender. Lower profile devices and those that accommodate higher neck angulation are expected to expand EVAR eligibility further for women. EVAR eligibility is unlikely to be lost as AAAs enlarge to 5.5 cm in women and 6.5 cm in men. Observation of small AAAs until they reach the standard threshold size for repair should not compromise EVAR eligibility. (J Vasc Surg 2011;54:931-7.)**

Two large randomized control trials of endovascular vs open repair of abdominal aortic aneurysm (AAA) have shown that periprocedural mortality is significantly reduced with endovascular aneurysm repair (EVAR).[1,2] Women were under-represented in these trials, comprising only 9% of the study populations. Similarly, clinical trials of EVAR devices with current United States Food & Drug Administration (FDA) approval contained 6% to 13% women,[3-7] despite data indicating that 21% of AAAs occur in women in the United States.[8] In both the randomized and pivotal trials, strict anatomic enrollment criterion may have reduced the number of female patients. Data from the National Inpatient Sample revealed that women undergoing elective AAA repair are less likely to be treated with EVAR than are men.[9] A review of the National Surgical Quality Improvement Program (NSQIP) database revealed that women had higher perioperative morbidity and mortality after EVAR despite adjustment for numerous clinical covariates.[10] Furthermore, several reports of small cohorts from individual centers have reported that women treated with EVAR had shorter, more angulated infrarenal necks as well as small iliac arteries, resulting in an increased incidence of treatment with EVAR outside the device's Instructions for Use (IFU).[11-13] These studies suggest that anatomic features are an important reason for the decreased use and worse outcomes of EVAR in women. The

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anatomic data in these studies, however, are limited by significant selection bias. Detailed, adjusted anatomic data from population-based samples are needed to better understand the differences in AAA anatomy and EVAR eligibility between men and women. Ultimately, such data may better inform future stent graft design, testing, and evaluation; increase the percentage of patients who are candidates for EVAR; and improve device efficacy.

The Characterization of Human Aortic Anatomy Project (CHAP) is a collaboration of clinicians and the FDA with a goal to better characterize aortic anatomy in the context of endovascular aortic devices. This study is the first of a series examining aortic anatomy as it relates to current and future endovascular device development.

The purpose of this study was to quantitatively describe the differences in AAA morphology between men and women in a large case series using anatomic measurements by blinded observers with high quality three-dimensional (3-D) computed tomography (CT) imaging. Specifically, anatomic characteristics between men and women were compared with respect to criterion in the IFU for FDA-approved devices to determine the relationship between gender and the potential for on-label use of EVAR. An additional specific purpose was to assess the relationship between gender, IFU eligibility, and AAA size, as it has been suggested that observation of small AAAs in men and women reduces the likelihood of successful EVAR.

PATIENTS AND METHODS

This study was conducted under approval by the local Institutional Review Board (Committee for Protection of Human Subjects). We obtained the complete dataset of all CT scans with 3-D reconstructions for AAAs between 1997 and 2009 at Dartmouth Hitchcock Medical Center (DHMC). CT angiograms to assess AAAs were prospectively submitted for 3-D reconstruction and analysis by blinded third party observers (M2S, West Lebanon, NH). For the large majority of this period, all scans evaluating AAAs were routinely submitted for 3-D reconstruction if there was a consideration of open or endovascular repair.

DHMC serves as both a primary care hospital for the local area as well as a tertiary referral center for the surrounding northern New England region. Approximately 65% of patients referred to the Section of Vascular Surgery come from our local area and 35% are referred by general or vascular surgeons in the outlying communities for tertiary care. This creates a case mix enriched with complex referral cases, but dominated by population-based characteristics. This dataset will act as a reference for future multicenter analysis within the scope of CHAP.

Reconstructions and measurements were obtained by a trained technician blinded to the proposed treatment using proprietary software. Technicians are monitored with acceptance criteria of variation between measurers (interobserver variability) of 2 mm for aortic and iliac diameters, 3 mm for maximal sac diameter, 5 mm for long centerline lengths (over 10 cm), 3 mm for apposition lengths, and 10 degrees for angles (M2S personal communication). These ranges are equivalent or superior to published interobserver variability for clinicians.[14]

Each CT scan was reviewed for a prespecified set of 23 anatomic measurements initially determined in conjunction with the Society for Vascular Surgery reporting standards[15-19] and the FDA/Center for Devices and Radiological Health), which is publicly available (http://www.m2s.com). Diameter measurements are made orthogonal to the center line access of the vessel and extend from the outer wall to outer wall. The infrarenal neck is defined by the orthogonal CT cross section immediately distal to the lowest lying renal artery measuring ≥3 mm and, by definition, continues until the aortic diameter changes by >10%. Accessory renal arteries smaller than 3 mm were not measured. The maximal aortic neck diameter was the largest diameter within the first 15 mm or within the available proximal seal zone, whichever was shorter (ie, for a 10-mm long neck, the maximum aortic neck diameter had to be within the first 10 mm beyond the lowest renal artery). Infrarenal neck angulation is the angle between the longitudinal axis of the infrarenal neck and the body of the AAA defined from the end of the neck to the aortic bifurcation.[15,16,20] Tortuosity index is a ratio of the centerline to straight line distance between the lowest lying renal artery and the ipsilateral femoral bifurcation reported as a percentage increase.[15,16] The minimal lumen diameter of the external iliac artery was used for assessment of adequacy of iliac access.

The analysis began with the complete dataset of measurements from CTs with 3-D reconstruction of the aorta from DHMC. All scans identified as being postoperative or of thoracic aneurysms were excluded, reducing the number available for analysis from 6767 to 2566. Due to M2S categorization methods, the remaining dataset included patients with thoracoabdominal aortic aneurysms, as well as patients with a primarily thoracic aortic aneurysm but also a concomitant AAA. To eliminate these patients, we subsequently excluded all cases of aneurysm involving the aorta at the renal level (defined as having an aortic diameter >40 mm at the renal orifices), aneurysms with a maximal aortic diameter <4 cm, and AAAs with maximal diameter between 4 and 5 cm if the maximal size was less than twice the diameter of the normal aorta at the renal artery level. This identified patients being evaluated for repair and those that might be expected to have repair within a few years. For AAAs with multiple 3-D datasets, we then identified and retained only the most recent scan before any intervention, if an intervention had occurred.

Before multicenter data analysis in CHAP, a limited number of single center analyses will be performed in order to test the analytical methods on a dataset that can be unblinded if necessary (eg, to evaluate outliers). To evaluate the mathematical "filter" criteria that may ultimately be used in a fully blinded multicenter CHAP dataset, CT scans for all 140 patients with infrarenal neck diameter 30 to 40 mm were individually reviewed. Seventy-four (53%) were excluded (53 suprarenal aneurysms, 9 with prior open repair, 12 due to incomplete data). The remaining 66 patients were included in the final analysis. A similar review was performed on a random sample of 80 CT scans. Of these 80, only two patients' (2.5%) scans were excluded,

Table I. Patient cohort data (mean ± SD)

	Men	*Women*	P *value*
Number (%)	812 (76)	251 (24)	
Age (years)	74 ± 9	77 ± 8	< .0001
Maximum sac diameter (mm)	59 ± 12	58 ± 10	.15
Neck diameter (mm)	25 ± 4	24 ± 4	< .0001
Neck length (mm)	19 ± 12	15 ± 12	< .0001
Infrarenal neck angle (degrees)	40 ± 16	48 ± 18	< .0001
Suprarenal aortic angle (degrees)	20 ± 13	28 ± 19	< .0001
External iliac artery diameter (mm)	7.0 ± 1.6	5.6 ± 1.3	< .0001

one patient had a prior open AAA repair with proximal aneurysmal degeneration, and one patient had a suprarenal aneurysm. After all exclusion criterions had been used, 1063 unique, unrepaired AAAs remained for analysis.

This selection process was intended to identify consecutive cases of infrarenal AAA (normal aorta at the renal level) with a complete set of measurements, whether patients were ultimately selected for open repair, EVAR, or observation.

Instructions for use vary for different commercial endografts. The common IFU criterion of all four commercially available bifurcated endovascular stent grafts were used: an infrarenal neck diameter of 18 to 32 mm, infrarenal neck length of at least 15 mm, infrarenal neck angulation of <60 degrees, and iliac access lumen of at least 6 mm. Iliac tortuosity and calcification are not accounted for in this analysis of iliac accessibility. Iliac artery aneurysm was defined as a common iliac diameter exceeding 20 mm.

Statistical analysis was performed using Stata (Stata V 9.2, Statacorp, College Station, Tex). Descriptive statistics of median and interquartile ranges (25th and 75th percentiles) are reported. Comparisons among AAA size categories were made using analysis of variance. Comparisons between continuous variables were made using *t* test and adjusted comparisons used linear regression modeling. Logistic regression models were used to perform adjusted comparisons of nominal variables.

RESULTS

The patient cohort is described in Table I. This unadjusted analysis demonstrates that women with AAAs have shorter and more angulated infrarenal aortic necks, more angulated suprarenal aortas, and smaller iliac arteries. Patient age and AAA size are also thought to affect aortic diameter and overall morphology, so these factors were taken into account in the analysis. Even after adjustment for patient age and AAA size, the mean AAA neck in the female cohort was 3.4 mm (95% confidence interval [CI], 1.5-5.2) shorter in length, 1.3 mm (95% CI, 0.7-1.8) narrower in diameter, and 8.6 degrees (95% CI, 6.2-10.9) more angulated than in the male cohort ($P < .001$ for each measure). The median measures of AAA neck anatomy by AAA size are reported in Table II.

Multivariate logistic regression modeling shows that older patient age (odds ratio [OR], 0.84 per decade), increased maximal aneurysm diameter (OR, 0.70 per cm), and female gender (OR, 0.4) are each independently associated with decreased odds of meeting all three device IFU criterion for the aortic neck ($P < .05$ for age, gender, and diameter). The percentages of patients who met each IFU anatomic criterion are listed by gender and AAA size category in Table III. A short infrarenal neck length was the most likely reason to exclude a patient of either gender from meeting IFU criterion. Small iliac access was the second most common reason followed by neck angulation. After exclusion of suprarenal AAA, neck diameter was rarely a cause for exclusion for EVAR of infrarenal AAA.

Bilateral iliac luminal diameters >6 mm were seen in 70% of men and 38% of women. Bilateral minimum iliac lumen diameters <6 mm were seen in 17% of men and 47% of women (Table IV). Among men, 13% had unilateral and 17% had bilateral iliac artery lumens smaller than 6 mm. Among women, 15% had unilateral and 47% had bilateral iliac lumens smaller than 6 mm in diameter. Unilateral iliac arteries over 20 mm were seen in 2% of women and men, and bilateral iliac arteries >20 mm were seen in 5% of women and 7% of men. These would likely not exclude most patients, but would rather infer extension into the external iliac artery for sealing. Only 32% of men and 12% of women met all three infrarenal neck criterion and had bilateral iliac artery lumen diameters over 6 mm.

Fig 1 demonstrates the decline in EVAR eligibility according to neck anatomy with increasing AAA size by patient gender. The change was statistically significant by a test of trend ($P < .01$). The largest drop-off in EVAR eligibility by neck anatomic criterion occurs above 5.5 cm in women and 6.5 cm in men. These changes in eligibility seem to be driven by neck length and angulation. Among women, 22% lose eligibility due to angulation and 13% due to neck length as they exceed the 5.5 cm threshold. Iliac access diameter and aortic neck diameter do not change significantly beyond the 5.5 cm threshold.

Sensitivity analyses describe the expected gains in EVAR eligibility with adjustment of a single IFU anatomic criterion while holding the other anatomic criteria at their current threshold. These comparisons reveal that reducing the criteria for neck length to 7.5 mm while leaving the other criteria unchanged will increase EVAR eligibility from 46% to 70% in men and from 25% to 45% in women (Fig 2). Decreasing delivery system profiles to fit through 5.5 mm (17F outer diameter) iliac access bilaterally would enable device delivery in 50% of women without a conduit or other type of dilation, assuming neck anatomy were held constant (Fig 3). Increased tolerance of a 90 degree neck to AAA angle would increase eligibility of men from 46% to 51%, and would increase women from 25% to 32%. While small in absolute terms, this would be a 28% relative increase in EVAR eligibility. Aneurysms with angulated necks frequently had concomitant short proximal seal zones, so increases in tolerance of neck angulation without improved tolerance of short proximal seal length does not change

Table II. Median neck measurements (IQR) by gender and AAA size category

	Maximal aneurysm diameter				
	4-5 cm (n = 147)	*5-5.5 cm (n = 317)*	*5.5-6.5 cm (n = 382)*	*>6.5 cm (n = 217)*	P *value*
Neck length (mm)					
Men	16 (10-28)	19 (10-30)	17 (9-27)	11 (6-21)	<.001
Women	12 (8-26)	15 (6-23)	10 (6-20)	7 (4-22)	.12
Neck diameter (mm)					
Men	26 (24-28)	24 (22-26)	25 (22-27)	26 (23-29)	.28
Women	25 (24-27)	23 (20-26)	24 (21-26)	23 (22-28)	.87
Neck angulation (degrees)					
Men	33 (23-41)	36 (28-46)	37 (28-50)	49 (33-61)	<.001
Women	32 (23-43)	41 (30-53)	53 (42-62)	61 (48-73)	<.001

AAA, Abdominal aortic aneurysm; *IQR,* interquartile range.

Table III. Percentage of patients meeting IFU neck criterion by patient gender and AAA size category

	Maximal aneurysm diameter				
	4-5 cm	*5-5.5 cm*	*5.5-6.5 cm*	*>6.5 cm*	*Entire cohort*
Neck length ≥15 mm					
Men	55	59	57	38	53
Women	36	48	35	30	37
Neck diameter 18-32 mm					
Men	96	97	96	91	95
Women	100	90	89	83	90
Neck angulation ≤60 degrees					
Men	97	92	89	75	88
Women	94	89	67	45	74
Meet all three neck criterion					
Men	52	54	48	29	46
Women	36	37	19	5	25

AAA, Abdominal aortic aneurysm; *IFU,* Instructions for Use.

Table IV. Iliac artery measurements by gender and AAA size category

	Maximal aneurysm diameter				
	4-5 cm	*5-5.5 cm*	*5.5-6.5 cm*	*>6.5 cm*	*Overall cohort*
Bilateral iliac diameter <6 mm (%)					
Men	15	17	23	17	19
Women	42	54	49	55	51
Either iliac diameter >20 mm (%)					
Men	19	17	19	25	20
Women	15	10	5	15	10
Bilateral iliac diameters 6-20 mm (%)					
Men	68	68	61	60	64
Women	45	41	45	33	42
Mean tortuosity index (%)					
Men	23	23	25	30	27
Women	22	23	27	33	26

AAA, Abdominal aortic aneurysm.
By analysis of variance, *P* values are not statistically significant.

overall eligibility as much as would be expected when considering the angulation parameter alone.

DISCUSSION

This is the largest study to date of aorto-iliac anatomy in a consecutive series of patients with abdominal aortic aneurysms. Notably, the series includes patients that had open repair or observation, as well as EVAR, so as not to bias the anatomic evaluation. This study shows that infrarenal aorto-iliac anatomy in women differs significantly from that of men, even when controlling for age and aneurysm size. Our analysis confirms the finding that

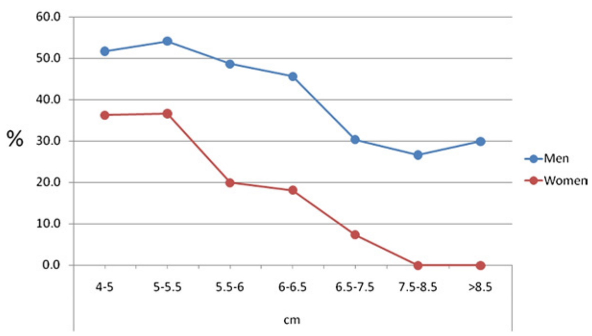

Fig 1. Percentage of patients by gender who meet all three neck Instructions for Use (IFU) by maximal abdominal aortic aneurysm (AAA) sac diameter ($P < .01$ by test of trend).

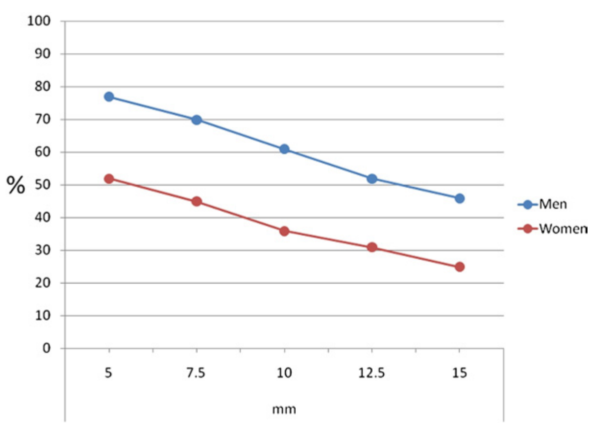

Fig 2. Percentage of patients who would meet Instructions for Use (IFU) criterion as mandatory neck length is shortened, holding other neck IFU criterion constant.

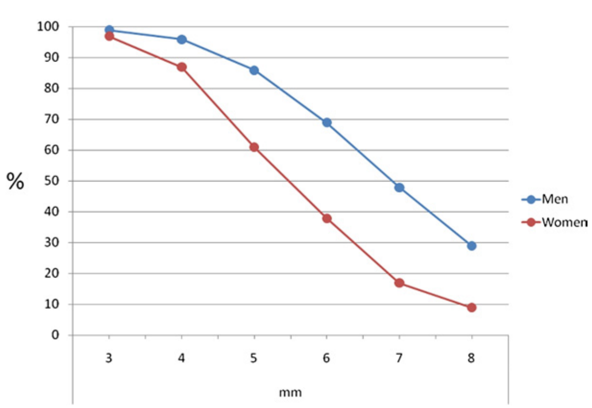

Fig 3. Percentage of patients with bilateral iliac diameters above given diameter.

women are much less likely than men to meet device IFU criterion for current endovascular devices due to decreased neck length, increased neck angulation, and small iliac access. These anatomic differences exclude a substantial majority of women from meeting current device IFU anatomic criterion.

In one of the first reports of EVAR eligibility by patient gender, Velasquez et al[21] reported that among the 19 women studied, only 7 met IFU criterion for early generation devices. Another early large single center report demonstrated that among the 29 women treated with EVAR, the necks were narrower and shorter and the iliac diameters were smaller.[12] The initial trial data with the Zenith device (Cook, Inc, Bloomington, Ind) demonstrated that women were more likely to have small iliac arteries and angulated infrarenal necks.[11] A large single center experience reported that women were more often treated outside IFU criterion due to neck length (7.1% vs 1.3%) and angulation (3.5% vs 0.7%).[13] A review of the NSQIP database revealed that women had higher perioperative morbidity (17.8% vs 10.6%; $P < .001$) and mortality (3.4% vs 2.1%; $P = .014$) despite adjustment for numerous clinical covariates, and the authors speculated that this was related to anatomic differences, noting a higher incidence of iliac conduits and brachial access in women (2.8% vs 1.0%; $P = .009$).[10] Abedi et al[10] did not have access to detailed anatomic information to confirm this hypothesis. Our results corroborate findings that suggest significantly different anatomy in women, and it differs with the findings of two early reports that suggest patient gender did not affect EVAR eligibility.[22,23] This study represents the first large case series, including consecutively enrolled unrepaired aneurysms to corroborate the aforementioned findings and hypotheses. We feel it is important that the measurements were performed prospectively by a blinded third party using high quality 3-D reconstructions and standardized measurements, with no bias to try to fit the anatomy into the inclusion criterion. Patients who had observation and open repair are included in an effort to reflect all patients with aneurysms rather than a selected EVAR subset. Our study population appears to reflect the U.S. population prevalence of AAA, as 24% of the patients in this study are women, similar to the 21% found in a nationwide AAA screening study.[8] These data, therefore, should more accurately reflect true anatomic differences for AAA in women, without the biases of preselection for EVAR. Furthermore, this study quantitates the influence of neck angulation and iliac access on EVAR eligibility among women and provides estimates of gains in eligibility if newer devices were constructed with different IFU criterion.

It is important to distinguish between the IFU criterion for neck and iliac anatomy. Adverse iliac anatomy, although potentially hazardous, is often amenable to adjunctive techniques (such as iliac conduits or aorto-uni-iliac devices) that will enable EVAR to be performed safely and effectively. Conversely, hostile neck anatomy has been associated with adverse outcome in a number of studies.[24,25] Although many patients are currently being successfully treated outside IFU criterion, the outcome of such use is less well characterized.[26] It is not appropriate to assume that the results of large randomized trials will apply to patients treated outside the IFU, as the large trials to date have not had a percentage of women that correlates with the prevalence in the population or even the percentage repaired in national databases. The performance characteristics of these devices have not been adequately tested and reported outside of the IFU criterion, and, therefore, we lack data to precisely predict their performance in these conditions. Given the early-term benefits in morbidity and mortality for EVAR, clinicians are left with a difficult choice in patients who are not good candidates for open repair yet do not fully meet the IFU criterion for currently available devices. This is especially true for women who have higher mortality rates than men with both EVAR and open repair, and a threefold higher risk of rupture while under surveillance.[27,28] Giles et al[29] demonstrated a 50% higher relative mortality risk for women undergoing either open or endovascular repair in a multivariate model using the Medicare database.

Last, there has been speculation that performing EVAR earlier (ie, at a smaller AAA size threshold) will eliminate some of the aforementioned problems with meeting IFU criterion. This speculation is based on smaller studies suggesting that AAA anatomy becomes less suitable for EVAR in larger aneurysms. Our study demonstrates that indeed larger aneurysms are less likely to meet the IFU criterion for EVAR. However, the drop-off in terms of percentage of patients meeting EVAR criterion occurs at 5.5 cm in women and 6.5 cm in men. These data expand upon the findings of a recent non-gender-specific study of 168 patients proposing a 5.7 cm threshold at which EVAR eligibility decreases.[30] Based on the current data, there is a low likelihood that a patient will lose eligibility for EVAR if his or her AAA enlarges to the 5.5-cm standard threshold for repair, especially if using a smaller threshold of 5 cm for women based on the U.K. Small Aneurysm Trial data.[27,28] A study of serial imaging data would be preferable to show this, but certainly there is no clear justification for repair at a small size based on the current data or the randomized Positive Impact of Endovascular Options for treating Aneurysms Early trial data.[31]

There are limitations to these data. The dataset does not include all clinically relevant anatomic features, including plaque thickness, calcification, mural thrombus, common iliac occlusive disease, accessory renal arteries, or iliac tortuosity. Furthermore, the ultimate determination of EVAR eligibility is a clinical one based on an experienced physician's review of the patient's condition and preoperative imaging. Anatomic limiters such as neck length and angulation are evaluated in conjunction with one another and in the context of the entire AAA anatomy. These complex anatomic interactions may further reduce the likelihood of EVAR eligibility, so these data may overestimate EVAR eligibility with strict adherence to IFU criterion. The iliac diameter measurement is a focal point estimate of the external iliac and is an incomplete descriptor of the adequacy of iliac access. Furthermore, there is known interobserver variability that persists despite highly trained unbiased observers, although this variability should be similar for men and women. As a single center study from a regional referral hospital, the results of this study cannot be extrapolated to all patients with AAA. Future multicenter projects with CHAP will hopefully further our understanding of these issues. These data are cross sectional, so inferences made about the relationships between AAA size and neck anatomy reflect those associations across a large population of patients rather the longitudinal behavior of any single AAA.

CONCLUSIONS

Women are less likely to meet IFU criterion for EVAR than men. Short neck length remains the main limiter of EVAR for both men and women, but future stent graft designs accommodating 90 degrees of neck angulation and utilizing 16F to 18F outer diameter delivery systems will also substantially increase on-label use of EVAR, especially in women. The percentage of patients with AAA that meet IFU criterion diminishes rapidly as the AAA size exceeds 5.5 cm in women and 6.5 cm in men, but it seems that observation of AAAs up to standard thresholds for repair is unlikely to change EVAR eligibility substantially.

AUTHOR CONTRIBUTIONS

Conception and design: MS, MF, TM, DA
Analysis and interpretation: MS, MF
Data collection: MS, MF
Writing the article: MS, MF
Critical revision of the article: MS, MF, TM, DA
Final approval of the article: MS, MF, TM, DA
Statistical analysis: MS
Obtained funding: Not applicable
Overall responsibility: MF

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